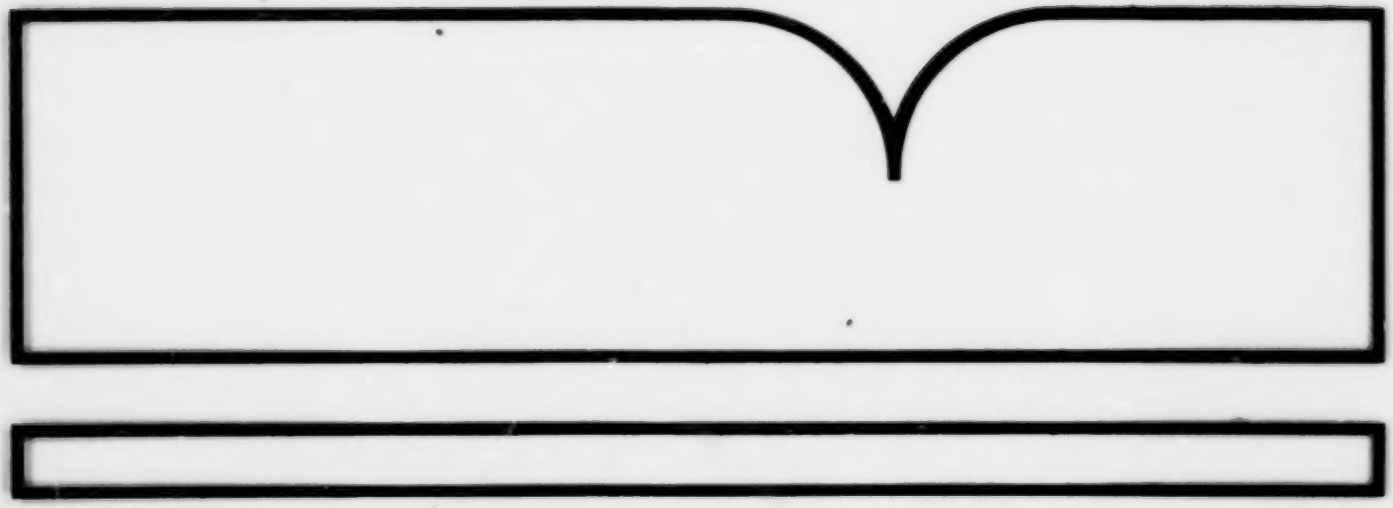
PB85-170157

RISK ASSESSMENT AND MANAGEMENT: FRAMEWORK FOR DECISION MAKING

Office of the Administrator
Washington, DC

Dec 84



U.S. Department of Commerce
National Technical Information Service
NTIS

PB85-170157

United States
Environmental Protection
Agency

EPA 600/9--85--002
December 1984

EPA

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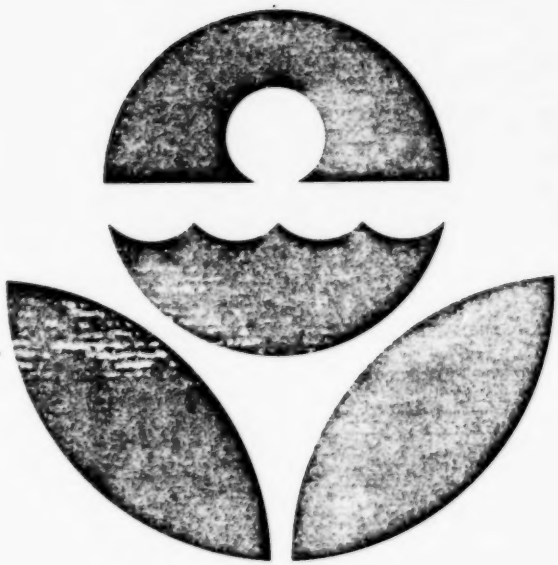

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TECHNICAL REPORT DATA
(Please read Instructions on the reverse before completing)

1. REPORT NO.	2.	3. RECIPIENT'S ACCESSION NO.
EPA/600/9-85/002		PB85 170157/AS

4. TITLE AND SUBTITLE	5. REPORT DATE
Risk Assessment and Management: Framework for Decision Making	December 1984
	6. PERFORMING ORGANIZATION CODE
7. AUTHOR(S)	8. PERFORMING ORGANIZATION REPORT NO.
9. PERFORMING ORGANIZATION NAME AND ADDRESS	10. PROGRAM ELEMENT NO.
	11. CONTRACT/GRANT NO.
12. SPONSORING AGENCY NAME AND ADDRESS Office of the Administrator U.S. Environmental Protection Agency Washington, DC 20460	13. TYPE OF REPORT AND PERIOD COVERED
	14. SPONSORING AGENCY CODE EPA/600/24

15. SUPPLEMENTARY NOTES

16. ABSTRACT

The risk assessment and risk management initiatives described in this report are tools which will help make possible more efficient protection of the environment and human health. We expect to gain the following specific management advantages:

Risk assessment and risk management help set priorities. There are thousands of chemicals in commerce and an unknown number of contaminants and unintended by-products. Some of these could be important as pollutants, and as such, are proper targets for regulation if they pose significant risks to health or the environment. We do not have the budget, nor will we ever have the time, to test each chemical exhaustively.

Screening by estimates of potential risk reduction is an attractive basis for comparing regulatory priorities. We can use risk analytic methods to help sort problems in terms of the likelihood that the Agency can do something constructive and effective to improve public health and the environment.

Risk management provides a context for balanced analysis and decision-making. Toxic chemicals are legitimately frightening: they can and do cause cancer and other diseases. The trouble is that we are exposed to a complex, highly dilute mixture of chemicals, taken in through air, water, and food. When disease strikes, cause and effect are seldom clearly linked. The Agency can contribute to rational discussion by exposing the scientific basis for the risk, including the confidence we have in the estimate; placing the risk reduction expected from the regulation in context with other risks and other opportunities for risk reduction; and explaining the values on which the balancing judgments have been made.

Risk assessment and management produce more efficient and consistent risk reduction policies. EPA's patchwork of authorities for controlling pollution needs to be woven together more coherently, beginning at the analytical level and continuing through to the regulatory decision. Some important differences - defined by statute - in the ways the laws manage risk will always remain, but a risk management approach can use our remaining administrative flexibility to make more efficient use of the Agency's and society's resources to reduce risk and to make the Agency's actions more consistent.

17. KEY WORDS AND DOCUMENT ANALYSIS

a. DESCRIPTORS	b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group

18. DISTRIBUTION STATEMENT	19. SECURITY CLASS *(This Report)*	21. NO. OF PAGES
RELEASE TO PUBLIC	UNCLASSIFIED	41
	20. SECURITY CLASS *(This page)*	22. PRICE
	UNCLASSIFIED	

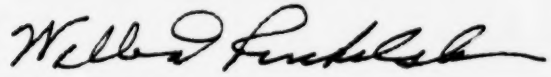
PREFACE

The National Academy of Sciences, in its 1983 report on Risk Assessment and Risk Management, provides a great service to those of us in the business of protecting public health and the environment. The report offered a clear distinction between the role of science in helping us assess the nature and extent of health and environmental problems, and the role of government managers in determining the most appropriate responses to those problems. Perhaps even more important, the report suggests a number of ways in which regulatory decision-making can be made more consistent and rational and, thus, more understandable and acceptable to the American public.

In a speech to the National Academy of Sciences soon after my return to EPA, I proposed that the Agency adopt as many as possible of the report's risk assessment and risk management goals. And we have. The Environmental Protection Agency has initiated a very wide range of activities designed to implement Academy recommendations. These activities are detailed in the following pages.

These new initiatives reflect our larger purpose to not only strengthen the scientific basis upon which we take regulatory action but to also make clear the necessary distinction that must be made between the definition of an environmental risk and what is done to reduce that risk.

But our most fundamental belief is that the public needs to understand fully how we intend to go about the business of reducing risk in our society. This report is meant to aid that understanding.



William D. Ruckelshaus
December, 1984

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CHAPTER ONE

INTRODUCTION

A. PURPOSE OF THIS REPORT

This report is about risk assessment and risk management at the Environmental Protection Agency. In recent months both terms have been used extensively in public statements by senior Agency officials and by the press in reference to many aspects of EPA's work. We hope to clarify here what these terms mean in the context of current Agency policy and operations.

Perhaps the most important thing any organization does is to reassess periodically how it can best fulfill its basic purposes and goals. Whether public or private, no institution can be successful unless it knows exactly what its business is, and how it intends to accomplish its mission. For EPA, a large organization with many complex responsibilities, being clear about both ends and means is essential. Controlling toxic chemical pollution is one of our most vital missions. This report presents our plans to enable the Agency to make better and more rapid decisions about environmental toxic chemical problems. This is not a technical report about the details of scientific research. Instead it discusses how we intend to manage the application of scientific research most effectively for making control decisions. Our audience is the general public, which needs to understand as much as possible about how we arrive at decisions to protect the environment and public health.

The goal of the Environmental Protection Agency is to improve the condition of the environment — to reduce risks to human health, and to protect and enhance the quality of natural ecosystems. This much has always been clear, but the more recently understood threat of toxic chemicals has greatly increased the difficulty of carrying out that assignment.

The job of reducing the risks of toxic chemicals is simply larger and more complex than anyone expected. For one thing, science allows us to detect ever smaller amounts of pollution. Air and water that seemed pure ten years ago are now revealed to be contaminated, even if only to a very small degree. Problems we once regarded as solved turn out not to be solved. Each new scientific revelation seems only to lengthen the agenda of possible actions. The number of issues to address is now so large that the first order of business is simply to separate problems from non-problems and grounded fears from ungrounded ones.

In the past there was widespread agreement over what the major environmental problems were, and how they should be controlled.

Municipal sewers were discharging untreated waste into the nation's rivers and streams, industrial stacks were emitting millions of tons of particulates and sulfur into the atmosphere unconstrained, and automobiles were discharging over ten times as much pollution per mile of travel as they do now. The total impact of this stress on the environment was not only clearly visible, it was an unambiguous threat to public health and well-being.

Congress responded by passing the Clean Air and Clean Water Acts, among other pieces of landmark legislation. Progress in treating the gross forms of pollution at which these laws were principally aimed has been remarkable. By any standard of measurement we have made vast improvements: the air and water are much cleaner than they were when EPA was set up in 1970. Our programs have set a standard that much of the rest of the world follows.

But the administrative tools that provided the first substantial measure of progress are not fully appropriate for addressing the qualitatively different problem of making decisions about controlling toxic wastes. As this report describes, our remaining pollution problems are numerous but more subtle. The economic consequences of addressing them are also potentially very great — perhaps as large or larger than those of the first round of environmental controls.

We cannot procrastinate in our mission of cleaning up toxic chemical pollution, but we cannot afford to make many mistakes either. Time wasted in chasing down the wrong chemicals is time wasted in controlling risks of cancer, birth defects, and other feared diseases. The issue is not simply one of dollars. Toxicology is a growing but still comparatively tiny field. We cannot be profligate with the research of the few experts we have; their time must be husbanded as the scarce commodity that it is.

Controlling toxic chemicals is ultimately a management problem. The scientific and technical issues are difficult, but no matter how much they are debated, the basic question is always what to do next. We need a new strategy that allows us to act constructively, despite the uncertainty that surrounds us.

These discussions describe the outlines of such a strategy. In the short term it envisions no drastic departures from past practice, but over the long term it should demonstrably improve our rate of progress in controlling environmental health risks. It will do this by aiming resources at the worst problems first, reducing the number of false moves, and helping to arrive at more consistent and practical courses of action.

B. PRACTICAL USE OF RISK ASSESSMENT AND RISK MANAGEMENT CONCEPTS

In a speech to the National Academy of Sciences, Administrator Ruckelshaus described the distinction between risk assessment and risk management:

> *"Scientists assess a risk to find out what the problems are. The process of deciding what to do about the problems is risk management. The second procedure involves a much broader array of disciplines, and is aimed toward a decision about control. Risk management assumes we have assessed the health risks of a suspect chemical. We must then factor in its benefits, the costs of the various methods available for its control, and the statutory framework for decision."*

The *distinction* between the two activities has become an attractive means for understanding and improving upon the two fundamental processes involved in environmental decisionmaking. This distinction was a major point in the NAS Report, *Risk Assessment in the Federal Government*, many recommendations of which are being considered for use at EPA.

But as Agency management has concentrated more attention on risk assessment and risk management during the past year, the question that has arisen is: how should our understanding of the distinction between these two concepts be used to guide the long-term management of the Agency?

The issue of Agency management is complicated by the peculiar nature of EPA's mandate: Implementation of eight major environmental statutes, each dealing with a different aspect of environmental protection, and each carried out with a history of considerable independence. Some of these statutes require or allow EPA to base its regulatory decisions directly on risk reduction. Other regulatory decisions, such as the control of toxic pollutants in the Clean Water Act Effluent Guidelines Regulations, are to be based on available technology and cost instead of risk reduction. Thus, while we are proposing risk reduction as the integrating concept for Agency management, we clearly intend to apply this approach only to the extent possible and reasonable within the constraints of the various statutes.

Additionally, risk assessment and risk management goals must be understood within the general context of the Agency's need to act. It is usually possible for the Agency to obtain more data with which to evaluate hazard, exposure, risk reduction efficiency of control strategies, and costs. This information, as is frequently said of pollution controls themselves, may take longer and cost more to

obtain, as precision and comprehensiveness increase. This in turn may mean that environmental and health costs incurred during the evaluation process increase. Thus, there must be a balance between the incremental costs of improved information and the benefits of regulating "more efficiently across program lines" especially where statutory considerations or political considerations may foreclose the more efficient options.

Program integration has always been a problem for EPA leadership because of the diverse mandates of the Agency. Nevertheless, such integration of environmental programs was one of the reasons for establishing EPA in the first place. Failure to coordinate has often led to management difficulties, including: duplicative research on the same substance; different programs producing different risk assessments for the same substance; unwitting transfer of pollutants from one environmental medium to another via pollution control technology; uncoordinated regulation of the same industry or the same substance by different programs; and seemingly different risk management decisions from different programs on the same substances.

For several reasons, program integration problems tend to be exacerbated by the increased attention the Agency must pay to toxic substances. First, the number of potentially toxic materials is extremely large. There are over 65,000 industrial chemicals listed as having been in commercial production since 1945. While many are not yet characterized as to their toxicological potential, a few thousand have some demonstrated toxic effect and are encountered in sufficient volume to be of concern. Many of these chemicals are of concern to more than one program, so that scientists and managers in different regulatory offices find themselves dealing with the same substances more often than in the past.

Next, since hazardous substances are often not destroyed or permanently isolated by actions meant to control them, it is necessary both to keep track of their movements — preventing pollution control from degenerating into an expensive shell game — and to make decisions about the most acceptable endpoint for persistent pollutants. This is important because some toxics may have effects on health at exceedingly small concentrations, so that in some cases it may be impossible to establish a level at which they present no risk at all. Hence, regulation must depend on some balancing approach.

These aspects of the toxics problem argue for a more integrated and readily comprehensible way to make regulatory decisions for the

Agency as a whole. More consistent risk assessments and improved risk management have thus become attractive as integration tools.

Neither risk assessment nor risk management is new at EPA. Nothing now planned is going to make these processes easier or less complex. They are inherently difficult things to do. *What we hope to accomplish by the current emphasis is to foster consistency using the best science and the best judgment across actions and across programs in both risk assessment and risk management, and to make the many judgments that lead to regulatory decisions more explicit.*

The essential requirement of a risk management approach is to demonstrate, to the extent possible, what each regulation *does* in terms of reducing risk. We wish to ask: when this regulation takes effect, will there be fewer deaths, less sickness, better visibility, more fish, safer drinking water? Risk management means that we will, for reasons connected with the changing nature of pollution control, try to make our actions more consistent across programs and more explicit in terms of environmental risk reduction.

The application of this concept of risk management works best when we can easily quantify, or express in defensible numerical form, the pollution risks Agency program offices are seeking to reduce through regulation. But we cannot, of course, quantify every value mandated by environmental statute nor can we reliably reduce to numerical form all risks of toxic pollution to health and the environment. Use of analytic techniques in risk management should not imply a false precision, and we will continue to take into account the need for qualitative judgment.

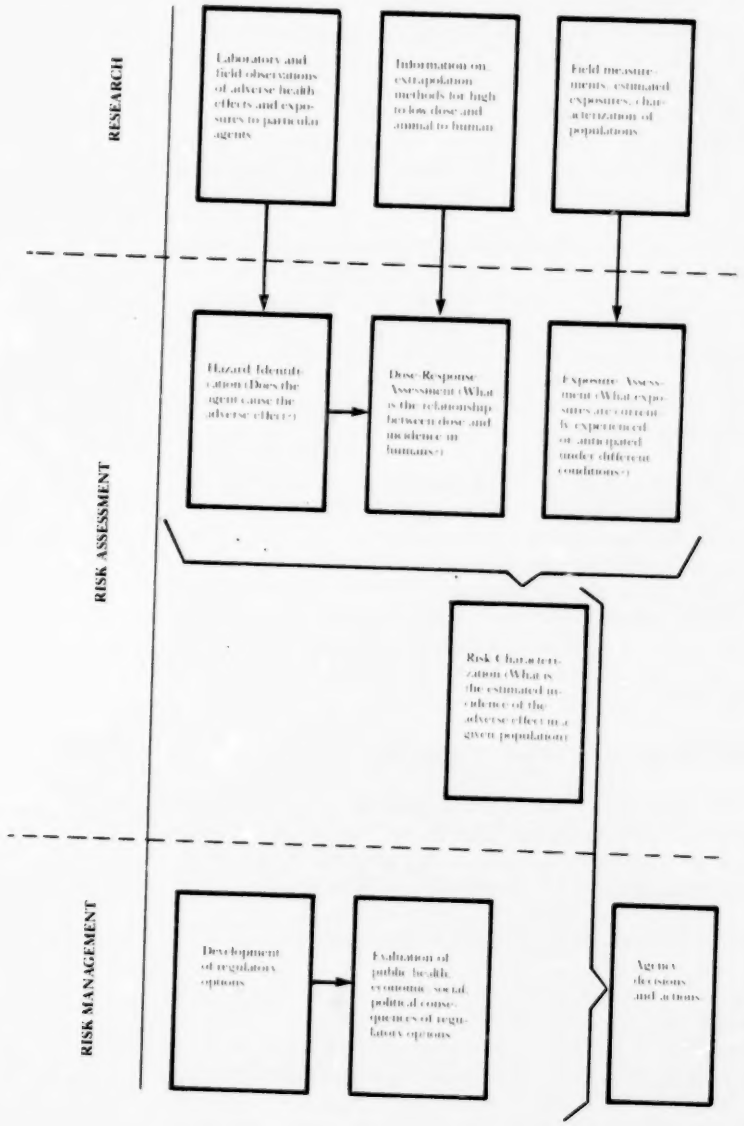
C. ADVANTAGES OF THIS APPROACH

The risk assessment and risk management initiatives described in this report are tools which will help make possible more efficient protection of the environment and human health. We expect to gain the following specific management advantages:

- Risk assessment and risk management help set priorities.

As already noted, there are now thousands of chemicals in commerce and an unknown number of contaminants and unintended by-products. Some of these could be important as pollutants, and as such, are proper targets for regulation if they pose significant risks to health or the environment. We do not have the budget, nor will we ever have the time, to test each chemical exhaustively.

ELEMENTS OF RISK ASSESSMENT AND RISK MANAGEMENT.


RESEARCH
Laboratory and field observations of adverse health effects and exposures to particular agents
Information on extrapolation methods for high to low dose and animal to human
Field measurements, estimated exposures, characterization of populations
RISK ASSESSMENT
Hazard Identification (Does the agent cause the adverse effect?)
Dose-Response Assessment (What is the relationship between dose and incidence in humans?)
Exposure Assessment (What exposures are currently experienced or anticipated under different conditions?)
Risk Characterization (What is the estimated incidence of the adverse effect in a given population?
RISK MANAGEMENT
Development of regulatory options
Evaluation of public health, economic, social, political consequences of regulatory options
Agency decisions and actions

Some of our priorities will always be set for us from outside, either by Congress or through the press of emergencies, but it would be foolish to suppose that the great underside of the iceberg will somehow take care of itself. We cannot escape the need for an analytic approach to setting our own agenda.

Screening by estimates of potential risk reduction is an attractive basis for such an approach. We can use risk analytic methods to help sort problems in terms of the likelihood that the Agency can do something constructive and effective to improve public health and the environment. It makes no sense to spend time and Agency resources to write regulations on chemicals, even highly toxic ones, to which no one will ever be exposed or for which there is no capability for additional control. On the other hand, it may make a great deal of sense to control chemicals that are only moderately toxic, if we have evidence that many people are exposed and that practical controls are possible.

- Risk management provides a context for balanced analysis and decision-making.

Toxic chemicals are legitimately frightening: they can and do cause cancer and other diseases. The trouble is that we are exposed to a complex, highly dilute mixture of chemicals, taken in through air, water, and food. When disease strikes, cause and effect are seldom clearly linked. Often the regulatory situation, in which any action may involve substantial health or economic impacts and in which the scientific basis is highly uncertain, allows extreme points of view to develop. This polarizes debate, sometimes bringing public policy to an impasse. The Agency can contribute to rational discussion by exposing the scientific basis for the risk, including the confidence we have in the estimate; placing the risk reduction expected from the regulation in context with other risks and other opportunities for risk reduction; and explaining the values on which the balancing judgments have been made.

- Risk assessment and management produce more efficient and consistent risk reduction policies.

EPA's patchwork of authorities for controlling pollution needs to be woven together more coherently, beginning at the analytical level and continuing through to the regulatory decision. Some important differences — defined by statute — in the ways the laws manage risk will always remain, but a risk management approach can use our remaining administrative flexibility to make more efficient use of the Agency's and society's resources to reduce risk and to make the Agency's actions more consistent.

Enhancing efficiency means, when appropriate, examining all available regulatory opportunities across all programs and selecting those that buy the most risk reduction for any given level of resources. It is also important to have consistent methods of assessing risk for the same substances across programs. Although our various mandates may require us to respond differently to risks that our calculations show are similar, we still need a consistent method for understanding the connection between our goals under the law and the actions we take. Further, unless we treat risks and their control consistently, we may fail to recognize opportunities to reduce risks in one arena that may contribute more to public health and the environment than further expenditures in another. Consistent policy-making based on well articulated principles is perhaps the most important element in creating a strong base of public understanding of Agency actions.

D. OUTLINE OF THIS REPORT

During the summer of 1983, Administrator Ruckelshaus and Deputy Administrator Alm began a number of efforts to investigate the issues associated with the assessment and management of risk and to start making necessary improvements to the regulatory process as a whole. One major initiative was the creation of the Toxics Integration Task Force, a group of senior agency scientists and managers. This group was asked to suggest practical improvements that could be implemented within existing organizational and statutory limits; its final proposals are all being implemented.

Some of this report is based on that work. The rest describes either analytic practices which have been evolving in the Agency over the past several years or other new initiatives in this area started in the past year by the Administrator and Deputy Administrator.

Chapter Two focuses on improving the scientific foundations for using risk assessment in the EPA regulatory context. It briefly describes the wide range of activities that the Agency uses to describe and quantify the effects of pollutants on human health and the environment. Assessments of risk are inherently imprecise — because knowledge is incomplete, and because the results of the process depend heavily on the procedures and assumptions used. The line separating "science" from "science judgments" is not a sharp one, in that judgment must be used where firm data are absent. In order to avoid the necessity for *ad hoc* judgments in individual cases, it is desirable to develop generic inference guidelines for different aspects of risk assessment. They also make the Agency's actions more predictable.

This chapter describes work underway to develop six new or revised risk assessment guidelines, and the creation of an internal risk assessment forum. The forum will resolve risk assessment disputes and will provide a mechanism for updating guidelines as new knowledge becomes available.

Chapter Three discusses current and new approaches for using risk management concepts in the regulatory process.

EPA's programs have differing mandates with respect to public health protection, and these bear significantly on the way the Agency deals with pollution control. The variety and uncertainty of risks from toxic substances makes exercising these mandates complicated and difficult. Risk management involves statements about values, and about the way that EPA interprets its statutory mandates. The public has a right to know what values the Agency is applying. This chapter describes several initiatives we are taking to articulate risk management within the regulatory development process, work we are doing to develop better analytic models for setting regulatory priorities, and recent progress in benefits assessment and regulatory impact analysis.

The actions described are only a start, but we believe they will bring significantly more clarity, structure, and predictability to the management of risks than has been the case up to now. We also hope they will be a step toward improving public trust in EPA's ability to address controversial matters of policy in a constructive and open way.

CHAPTER TWO

RISK ASSESSMENT: IMPROVING THE SCIENTIFIC FOUNDATION

EPA regulatory decisions address, of course, a wide range of possible pollutant effects. Human health concerns include genetic damage and neurological effects as well as cancer, and we consider such adverse environmental impacts as ecosystem disruption, crop damage, and atmospheric impairment. At present, however, the Agency has progressed further in developing procedural guidelines for human health risk assessment than we have for environmental effects. Also, our quantitative analytic techniques are most refined for cancer assessment. The focus of this chapter is mainly on innovations in the narrower area of human health risk assessment.

Health risk assessments are conducted by scientists, but they are not "classical science" in the strictest sense. For regulatory purposes, risk assessments represent a tool that can be used to analyze scientific evidence in order to evaluate the relationship between exposure to toxic substances and the potential occurrence of disease. The risk assessment process involves, on one extreme, scientifically verifiable findings, and, on the other extreme, judgments about the use of various kinds of scientific information. No one should be misled into believing that results using present techniques have the status of incontrovertible scientific agreement. Despite its uncertainties, however, risk assessment is the *only* tool we have for discriminating among environmental health problems. The central question we address here is the extent to which risk assessment judgments can be made more consistent and more reflective of the state of scientific understanding.

There is no constant formula for conducting a risk assessment. Because this is an analytical tool, it can be argued that it must be tailored to the needs of the program in which it is used. Given the different mandates within the Agency, it is not surprising that there are a variety of reasons for performing risk assessments and an equal variety of methods used to conduct them. Some examples follow to demonstrate the diverse nature of these assessments.

Risk assessments of carcinogens are assessments of risk in the literal sense, i.e., an estimation of the probability of developing cancer as a direct result of chemical exposure. Carcinogens are, by EPA policy, assumed not to have thresholds, i.e., no level of exposure is assumed to be without risk unless there is specific evidence to the contrary in a particular case. The data underlying

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such assessments typically involve doses to animals much higher than the exposure levels expected for the human populations of interest. Therefore, the risk assessments use probabilistic models to draw dose-response curves to extrapolate from the higher, experimental, dose levels, down to the zero exposure point. The product of this kind of assessment is an estimate of the probability (risk) that additional cases will be associated with some given exposure level. This probability is usually expressed as a unit dose value, or risk per unit of exposure, such as risk per part per million (ppm) of a substance in the air or in drinking water. This unit risk can than be multiplied by exposure levels and by the number of people exposed to generate estimates of excess cancer incidence associated with the exposure.

This approach to risk assessment can be used for studying any health effect where thresholds are assumed not to exist, provided that there exist adequate data to construct a dose-response curve. Note that efforts are underway (such as in the air program) to develop probabilistic risk estimates for noncarcinogens.

In other types of risk assessments, where a threshold effect is assumed for a toxic substance, the primary focus of the analysis may be to determine the "safe" or no-effect level of exposure. Information derived from animal experiments, or human data in cases where such data are available, is used to establish a "no-observable effect level" (NOEL) or "lowest observed effect level" (LOEL) for the substance in question. Such levels are then divided by uncertainty factors, which vary depending on the nature of the supporting data, to produce an acceptable exposure level. These resulting levels may be expressed as acceptable daily intakes (ADI). We assume that persons exposed to levels of pollutants below these acceptable exposure levels will not suffer adverse effects from the exposure. ADIs are then combined with any other available data regarding effects above the threshold level.

Risk assessments can also be used as a screening device for setting priorities, or as a method for quickly ranking the relative toxicities of large numbers of chemicals. This type of approach is usually less detailed, and typically involves some kind of health effects rating system. It is important, because formal risk assessment is slow and expensive, and quicker decisions are often needed on the handling of many chemical or regulatory problems. Two examples of this type of screening assessment are the Superfund hazard ranking system, and the methodology used by the Integrated Environmental Management Division in the Office of Policy, Planning and Evaluation. Also, the Office of Toxic Substances uses abbreviated risk assessment methods which rely heavily on structure activity

relationships to screen new chemicals that lack adequate toxicological information.

Where specific geographical areas have been contaminated with toxics, the Agency must respond with an assessment of the potential danger to people in the area and, in some cases, with estimates of the risks associated with various clean-up options. These assessments do not necessarily differ in kind from those mentioned above, but may involve more or less detail depending on the exigencies of the situation.

A. STRUCTURE OF THE ASSESSMENT PROCESS

In the simplest sense, population risks from toxic pollutants are a function of two measurable factors: hazard and exposure. To cause a risk, a chemical has to be both toxic (present an intrinsic hazard), and be present in the human environment at some significant level (provide opportunity for human exposure). Risk assessment interprets the evidence on these two points, judging whether or not an adverse effect will occur, and (if appropriate) making the necessary calculations to estimate the extent of total effects.

In a regulatory setting, risk assessment has one or more of the following four steps. One usually starts an assessment by considering hazard identification or exposure. If either is negative, one does not proceed.

1. Hazard identification

This exercise involves weighing the available evidence and deciding whether a substance exhibits a particular adverse health effect. Most attention has been focused on cancer, but we may also want to regulate on the basis of other effects, such as damage to fetuses (teratological effects), inherited conditions (mutational effects), and damage to specific organs such as the liver or kidneys.

The Drinking Water and Air programs, for instance, regulate lead on the basis of its neurotoxic effects, and the Toxic Substances program is considering regulation of glycol ethers on the basis of their teratogenic effects.

2. Dose-response assessments

Once it is determined that a chemical is likely to cause a particular human effect, we then determine its potency: how strongly it elicits that response at various levels of exposure (dose).

Chemical potency varies widely: for instance, both saccharin and dioxin cause cancer in animals, but it takes literally millions of times more saccharin than dioxin to produce equivalent effects in the laboratory (fortunately, real world exposure to dioxin is also much lower).

3. Exposure assessment

We then estimate the likely degree of human exposure to a chemical of concern. The best method is direct measurement or monitoring of ambient conditions, but this is often prohibitively expensive. In practice, we must usually rely on estimates of emissions and limited monitoring information, combined with mathematical models that estimate resulting concentrations.

The degree of exposure of concern may vary from pollutant to pollutant. For many effects, we may be primarily interested in lifetime exposures over the whole population; for others, we may be concerned about maximum levels of exposure to people near the emission source, or peak levels of short term exposure. We are also concerned with unusually sensitive portions of the population (children, the elderly, people suffering from respiratory or other particular illnesses).

4. Risk characterization

Finally, we estimate the risk associated with the particular exposures in the situation being considered for regulation. While the final calculations themselves are straightforward (exposure times potency, or unit risk), the way in which the information is presented is important. The final assessment should display all relevant information pertaining to the decision at hand, including such factors as the nature and weight of evidence for each step of the process, the estimated uncertainty of the component parts, the distribution of risk across various sectors of the population, the assumptions contained within the estimates, and so forth.

B. UNCERTAINTY IN RISK ASSESSMENT

Given the usual limitations in the nature and extent of information available in this process, we can never say exactly how many people will be affected by a particular pollutant, or how severely. Not enough is known about how pollutants contribute to certain diseases or about the nature of human exposure to make definitive findings possible.

Definable relationships occasionally exist between certain diseases and certain substances, as they exist, in a more verifiable way, between diseases and bacteria. The task of risk assessment is to make the most credible possible statements about these relationships, reducing uncertainty as much as possible, and making explicit whatever uncertainty remains.

This section discusses several of the types of uncertainty that occur at various stages in a risk assessment.

1. Weight of evidence problems in hazard identification

Most risk assessments depend on animal tests. These tests allow rigorous control over many factors that contribute to uncertainty, but some fundamental problems remain.

For instance, animal biological systems are different from human ones. Some species appear more sensitive to certain substances than humans, and less sensitive to other substances. Or we may find that a chemical is a strong carcinogen in various test animals, but it induces a type of tumor that humans do not get. Another chemical may be a carcinogen in only one animal species. Should we consider the chemical a human carcinogen?

2. Uncertainties in dose-response assessment

Despite existing scientific practice, it is not entirely clear that *safe levels or thresholds* truly exist for any toxic chemicals (or, indeed, that no threshold exists for carcinogens) and if so, at what levels. While immediate effects such as respiratory distress may not occur after short exposures to low doses, subtle damage to health *may* occur after long-term, low-level exposure and could do enough damage to the population as a whole to be worth controlling.

Also, as mentioned above, scientists must extrapolate dose-response relationships from animals to humans. Dosages must be corrected for human-animal differences in weight or metabolism. Effects at low doses must be inferred from high-dose results in laboratory or epidemiology studies. For cancer, results have typically been couched in terms of the maximum amount of excess disease that a chemical is likely to produce. This is a complex process, with uncertainties attached to every judgment and inference made. Because of its complexity and its heavy reliance on assumptions, dose-response estimation for carcinogens is a particularly controversial aspect of risk assessment. The Agency is continuing to explore new statistical approaches for more accurately representing dose-response evidence.

The Agency is not alone in its concern that different assumptions and different mathematical models used can significantly alter the outcome of a risk assessment. When the Occupational Safety and Health Administration (OSHA) published its cancer policy in 1980, it did detailed comparisons of how estimates of carcinogenic risk can vary with the assumptions used in developing the estimates (45 FR 5198-5200). By varying the method of low dose extrapolation used, and the toxicology or epidemiology study which formed the basis of the risk assessment, commenters to the OSHA policy developed risk estimates for exposure to 1 ppm of vinyl chloride which ranged from 10^{-8} (one in one hundred million) to 10^{-1} (one in ten, or 10%). A similar exercise with saccharin by NAS, and reprinted in the OSHA policy (45 FR 5200), estimated the expected number of cancer cases in the general population (exposed at 0.12 grams/day) at between 0.001 cases per million exposed, and 5200 cases per million exposed. These differing estimates were developed by using different low-dose extrapolation models and different animal-to-human extrapolation methods — all of which had some credence in the scientific community.

3. Uncertainty in exposure assessment

Thus far, exposure assessment has attracted less controversy than the other stages of risk assessment, but it also involves uncertainty.

Exposure assessment is based on human monitoring, ambient monitoring, modeling, or some combination of these. Human data and monitoring are typically quite limited, because we do not have the resources or time required to do scientifically valid studies for all the pollutants of concern.

Modeling is used to fill the gaps. In these techniques, data on pollutant releases, release characteristics, meteorology, hydrology, terrain, etc. are arranged and interrelated in mathematical models. Computers are used to calculate the distribution of pollutants in the ambient air and water at various distances from the pollutant sources. The population exposed to these chemicals is then estimated using census data, and information about drinking water sources and other exposure routes.

C. IMPORTANCE OF SCIENCE GUIDELINES

To make progress in the face of such uncertainties we must develop what the National Academy of Sciences report calls "inference guidelines." Despite scientific consensus endorsing such an approach, there is still debate about the degree to which standard

procedures can or should be defined and about the terminology involved in the process. The NAS report recommends, and we believe, that greater consistency in the risk assessment process is not only possible, but essential.

1. Principles

Assessments have historically been based on a number of underlying principles, such as the judgment that animal bioassays are indicative of probable human response, or that no threshold of response to carcinogens can be confidently defined. A statement of principles may include simple observations of fact, statements of broad-based scientific consensus, or judgments about "science policy." While debate continues in some areas, there is wide scientific agreement on most of the principles driving the assessment of cancer risk. The most comprehensive reference on the subject is the recent draft document by the Office of Science and Technology Policy, entitled *Chemical Carcinogens: Review of the Science and its Associated Principles.* This document, published for public comment in the Federal Register on May 22, 1984, provides a thorough and well-referenced review of current knowledge about the physical, chemical, and biological events underlying the process of tumor development. As yet, no similarly comprehensive reference on health effects other than cancer is available. Although general principles exist for approaching other types of risk assessment, there is still considerable uncertainty and disagreement about the details of how to relate pollutant exposures to the incidence of noncancer effects.

2. Guidelines

Statements of principle in themselves offer direction for conducting specific risk assessments, but they should be augmented by more specific technical guidance appropriate to regulatory needs. Attempts at more practical common approaches have therefore evolved in the various regulatory agencies over the last several years. General procedures for estimating risk (mainly in reference to cancer) have been codified in the form of guidelines, which include:

1. Interim Procedures and Guidelines for Health Risk and Economic Impact Assessments for Suspected Carcinogens, EPA, 41 FR 24102 (May 25, 1976).

2. Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks, Report by the Work Group on Risk Assessment of the Interagency Regulatory Liaison Group, 44 FR 39858 (July 6, 1979).

3. For a specific EPA program:

   Guidelines and Methodology Used in the Preparation of Health Assessment Chapters of the Consent Decree Water Criteria Documents, Appendix C of Water Quality Criteria Documents: EPA, 45 FR 79347 (November 28, 1980).

   See also:

   Appendix E: Response to Comments on the Human Health Effects Methodology for Deriving Ambient Water Quality Criteria, 45 FR 79368.

4. Mutagenicity Risk Assessments: Proposed Guidelines, EPA 45 FR 74984 (November 13, 1980).

5. Guidance for the Preparation of Exposure Assessments, EPA, Draft, September 12, 1983.

Conference proceedings on reproductive risks are also available at EPA, and we can use these proceedings to guide evaluations of risk in the absence of formal guidelines.

To be useful, guidelines must simultaneously balance the need to be comprehensive, specific, and flexible. *Comprehensive* means they should deal with each discrete step of a risk assessment. *Specific* means they must describe the scientific basis for each step, and how to perform it. And *flexible* means they must allow, even encourage, departure from the general approach if data are available suggesting that an alternative is preferable, or if a single approach is not appropriate to the case at hand.

During a recent brief review of current risk assessment practices throughout the Agency, we became concerned about two issues:

- Are there inconsistencies in risk assessments now performed by different groups within EPA, and if so, why?

- Should we have a more explicit, formal means for resolving scientific controversy, and for updating our practice as regards assessment procedures and assumptions?

These concerns have prompted two decisions: an Agency commitment to develop six risk assessment guidelines; and the creation of an internal Risk Assessment Forum. The remainder of this chapter describes work EPA has underway on those guidelines and the role of the new Forum.

D. DEVELOPING RISK ASSESSMENT GUIDELINES

In light of the NAS recommendations for developing risk assessment guidelines and procedures, we reviewed many of the technical issues that constitute the components of a risk assessment. These issues are numerous, diverse and cover a broad spectrum of potential problems.

To deal with problems like these, the Agency plans to complete new (or revise existing) guidelines on the following topics:

1. Carcinogenicity

The 1976 Interim Guidelines for Cancer Risk Assessment are being updated in order to reflect more recent developments in the scientific data base supporting the guidelines and the cancer principles in the OSTP documents, and to clarify points that are unclear or have been unresolved in the existing guidelines.

2. Mutagenicity

Mutagenicity refers to the potential of an agent to induce alteration in the genetic material of living organisms. These alterations may include point mutations (such as changes in the base sequence of DNA) and structural or numerical chromosomal aberrations.

The Agency currently evaluates mutagenicity data as a basis for possible chemical regulation. While this information is most often used to predict carcinogenic potential, increasingly such data are being used to predict potential for the induction of heritable mutations.

The Agency's existing draft guidelines for mutagenicity risk assessments describe the types of evidence to be weighed in determining the potential mutagenicity of a chemical, as well as quantitative approaches that may be appropriate to the estimation of human heritable mutation and disease. In preparing the revised mutagenicity guidelines, the Agency will review and update the proposed guidelines.

3. Reproductive effects

The male and female reproductive systems and the developing fetus are potentially sensitive targets for the action of toxic agents. Developmental toxicity is included in the category of reproductive effects and pertains to teratogenicity as well as other effects such as

to resorbed fetuses, stillbirths, spontaneous abortions and other congenital dysfunctions.

Teratogenic effects encompass an extremely diverse set of impacts that harm the developing fetus and are manifested as congenital malformations (such as cleft palate), developmental malformations, or functional malformations (such as nervous system dysfunction). The Agency has a preliminary document ("Assessment of Risks to Human Reproduction and to Development of the Human Conceptus from Exposure to Environmental Substances," EPA, 1982) outlining major issues for consideration in assessing both teratogenic and reproductive effects resulting from exposure to environmental agents. However, this document does not provide definitive guidelines for assessing such risks to the developing organism. At least two major issues need resolution:

- Existence of a threshold

Unlike carcinogens or mutagens, which may be presumed to have some finite probability of an effect at any dose, no matter how small, some teratogens may have an effect only if they exceed a certain level of exposure. Where thresholds are believed to exist, we want to be able to define a no observed adverse effects level, with appropriate safety factors. On the other hand, we also want to provide technical guidance for determining which assumptions to make.

- Extrapolation between species

Inherent interspecies differences complicate extrapolation of animal test data to direct determinations of human risk. For example, aspirin is a fairly powerful rodent teratogen and thalidomide is a fairly weak animal teratogen. The situation is, of course, reversed in humans.

4. Systemic effects

In addition to the effects previously discussed in this report, exposure to toxic substances can lead to adverse effects on various organs, such as the liver, the kidneys, or the lungs. These effects cover a broad spectrum of graded tissue responses ranging from small changes in enzyme levels to severe organ dysfunction and debilitation or death of the individual. Thus, we need some mechanism for interpreting data pertaining to the graded effects observed in a specific organ from exposure to a particular toxic substance.

Available scientific evidence indicates that many systemic toxic substances may have thresholds, which further complicates risk assessment. Moreover, the results of the calculations for estimating the threshold can vary depending on which one of the graded responses is used to represent the disease state. For example, if one wants to calculate a threshold for kidney effects due to cadmium exposure, it will make a difference if one looks at the early stages of the disease (i.e., mild cellular changes) or, assuming the disease progresses, at the later stages of the disorder (i.e., severe cellular changes and kidney dysfunction).

Current Agency draft guidelines for risk assessment of systemic toxicants only address the estimation of "safe" exposure levels, such as ADIs. Further development of these guidelines will focus on these key issues:

- Extrapolation of health effects in test animals to health effects in humans.
- Extrapolation of dose in test animals to equivalent exposure in humans.
- Comparison between different routes of exposure in test animals and humans.
- Ranking of graded toxic effects.

5. *Assessment methods for chemical mixtures*

Most risk assessments address the health impact of individual chemicals; the Agency has an increasing need to know the risks associated with chemical mixtures. The hazardous waste and Superfund programs, for instance, deal with exposure to mixtures more frequently than they do with exposure to single chemicals. We also know that people are typically exposed not to isolated pollutants, but rather to a complex, dilute mixture of many substances.

Considering how many chemicals there are in the environment, there is a virtually infinite number of combinations that could constitute potential synergisms or antagonisms. In only a few cases do we have concrete evidence of what these interactive effects might be. In the absence of such evidence, we use an additive method that simply sums individual chemical effects on a target organ. As we learn more about the effects of chemical mixtures, we may have to modify the additivity approach. The new guidelines will describe a hierarchy of procedures for estimating health risk, based on the

nature of the available data. The possible data types include: (1) specific toxicity data on the mixture itself, (2) toxicity data on a chemically similar mixture, (3) data on interactions of some of the components of the mixture, and (4) quantitative toxicity data on single chemicals within the mixture.

6. Exposure assessment

Given the absence of complete environmental data, we must estimate ambient levels of pollutants or chemical exposures using the following information sources, singly or in combination:

- measurements of actual tissue concentrations of pollutants;
- field monitoring;
- laboratory modeling data;
- mathematical modeling.

To estimate human uptake of some substance, the first step is to determine how many people are exposed through the various relevant environmental pathways — in the air, soil, water, drinking water, or food. The next step is to calculate the rate of uptake through breathing, eating, drinking, or absorption through the skin.

The new exposure guidelines will review, and modify as needed, the standard factors used in estimating exposure; for humans these factors include standard body weights, breathing rates, and fluid and food intakes. In the past, there have been some differences among programs; these have not been great, but they do contribute unwanted variation in the results of risk assessments. The guidelines will address statistical approaches designed to estimate the degree of uncertainty associated with different modelling assumptions.

E. ESTABLISHMENT OF A FORUM ON RISK ASSESSMENT ISSUES

We have established a Risk Assessment Forum to provide an institutional locus for the resolution of significant risk assessment issues as they arise, and to insure that Agency consensus on such issues is incorporated into the appropriate risk assessment guidelines. The Forum will also provide Agency scientists with a regular time and place to discuss problems of risk assessments in production. Peer advice and comment of this type will help improve the quality of risk assessments, with associated savings in time and resources.

CHAPTER THREE

GOALS AND APPLICATIONS OF RISK MANAGEMENT

A. DEFINING RISK MANAGEMENT

The NAS has defined the term risk management as the complex of judgment and analysis that uses the results of risk assessment to produce a decision about environmental action. The term was originally meant to distinguish the political, economic, and social aspects of decision-making from the scientific exercise involved in the assessment of risk. It has come in the last year or so to stand for a wider and potentially more useful concept as the Agency has begun to implement the National Academy of Sciences definition.

This chapter is about the Agency's application of that wider meaning. It defines what we hope to gain from the risk management approach to environmental protection: what current problems we are addressing with it and what our goals are. It also describes some of the changes in Agency procedures, operations, or objectives that have developed over the past several years or more recently, as a result of adopting the risk management approach suggested by the NAS.

If we regard risk reduction as one of EPA's main reasons for being, then we can define risk management as determining and accomplishing those actions that will reduce risk to the greatest degree given any particular level of resources, meaning Agency resources and those of society in general. The resource consideration is vital here. One can argue about how much should be spent on environmental protection, but at some point everyone must accept that the commitment of resources for any social purpose has a finite limit. If the number of potential risk targets is very large in comparison to the number we can realistically pursue, which seems now to be the case, then some rational method of choosing which risks to reduce and deciding how far we should try to reduce them is indispensable.

It is important to keep in mind that *while individual risk management decisions may be seen as balancing risk reduction against resources, the system as a whole is designed to balance risk against risk.* In other words, it is essential that we address the worst and most controllable risks first; failure to do so means that the total amount of harm that we prevent is smaller than the amount we might have prevented. Making incorrect priority choices, saving one where we might have saved two, represents a profound failure of the Agency's basic protective mission.

In making such balances, the risk management approach regards risks of the same type (e.g., risks of a particular disease) as comparable regardless of the route through which people are exposed to them. This makes sense because we know that risk may be transferred around the environment and among environmental media by natural processes or by pollution control itself, and the idea is, of course, to reduce the total risk in the whole environment.

In practice, however, this is extremely difficult to do, as EPA operates under eight major statutes, each directed at a different form or locus of pollution. These statutes not only establish the values that the Agency must protect (and these naturally differ among the statutes), but in the case of risk to human health, they often appear to direct different approaches to risk reduction. Briefly, there are two broad groups of statutory mandates to which any risk management approach must be adapted. In the first (e.g., Toxic Substances Control Act), explicit balancing of risks against benefits or costs of control is authorized or required. When applied in reference to programs under such laws, risk management is the analysis and exposition of the balancing considerations.

In the second group (e.g., the Clean Air Act), a standard that protects human health or some other value must be established or some particular level of technical control must be applied. Cost considerations may be specifically prohibited during the development of the protective standard. Here risk management means finding the most efficient way of achieving the standard, while at the same time assuring that policies designed to remove specific pollutants under these laws do not have perverse effects, such as transferring an equal or increased risk to another environmental medium.

Another difficulty arises because we are called upon by most of our statutes to protect a variety of environmental values, as well as human health. In general, it is more difficult to quantify risks to these environmental values (and reductions in such risks by regulatory action) than it is to come up with comparable estimates for human health risks. Protection of environmental values is of especially great importance in statutes such as the Clean Water Act. The special attention given to human health risk reduction in parts of this report is not intended to indicate any less concern for protection of environmental values, or any diminished intention to act to protect them; rather, it recognizes that risk assessment and the analytical approaches for risk management discussed here have progressed considerably further in their application to human health risk.

B. ELEMENTS OF RISK MANAGEMENT: SETTING PRIORITIES AND MAKING CHOICES

In operation within the Agency, the risk management approach has two major ends: setting priorities among the risks presented by pollution that are amenable to control by EPA; and choosing the appropriate reduction actions for the risks so selected. EPA's current risk management approach requires that these traditional activities be expressed, where feasible, in terms of risk reduction.

In the case of priority setting, this risk-based management ideally would enable us to insure that the Agency *as a whole* had an agenda of potential activities directed against the worst set of risks susceptible to its control. Priority-setting, in turn, is important because historically the Agency's agenda has been set less by systematic analysis than by direct public pressure in response to the environmental issues of the day, often embodied in court orders; diverse legislative mandates; or merely random action. To a certain degree, this reactive mode of behavior is inevitable. But it would be of tremendous advantage to the cause of real risk reduction if the Agency were able to make the case that its assemblage of proposed risk-reduction targets was a demonstrably more important one than any other set.

In choosing control actions, the Agency's discretion regarding the balancing of risks with other factors varies with the applicable statutes. Nevertheless, a certain amount of balancing goes on in virtually every important Agency control decision. Historically, this kind of judgment has taken place at many different levels and sections of the Agency; when policies or regulations reached the final stages it was often impossible to establish in any meaningful way the nature of the judgments that had gone into them. In contrast, in the risk management approach it is of the essence that such judgments be made as early and as explicitly as possible, and that the whole array of considerations that establish an Agency decision about controlling some risk be presented in a comprehensible fashion to senior EPA management.

In general, the balancing that goes into such risk management decisions includes consideration of at least three major components. The first is the harmful effect of the pollutant(s) proposed for control. When the effect is on human health this factor may be expressed as a numerical risk estimate, but EPA must control many harmful effects that cannot be so expressed. It is important to remember that the term "risk management" is used broadly enough to apply to these non-quantifiable effects as well.

Particularly difficult issues of value arise in connection with non-health effects. While we can quantify certain "benefits" that accrue when such effects are reduced (e.g., increased fishing days, reduced materials damage), clearly there are some values that defy this approach, yet are obviously important and, indeed, are built into the language of much of our legislation. The values include such considerations as the value of an unused aquifer or of the preservation of pristine wilderness areas. It is important to remember that risk management includes making judgments about values that do not involve human health risk and can not be quantified under the present state of the art.

The effects factor is therefore not a simple one. Besides the many complexities involved in assessing the extent of exposure and the severity of hazard (which have been discussed elsewhere in this report), the balancing decision should consider the distribution of the effect in terms of how many people it affects over how wide a geographic area, the reversibility or persistence of the effect, and the impact of the decision on the long-term health of ecological systems.

The second factor may be called "cost," although it is not simple either. It may include the cost of pollution controls, consideration of the effects of alternative practices, the relinquished benefits of using a pesticide or other toxic chemical, the danger of displacing private sector initiatives, or the impact of some control option on employment, firms, or communities.

The third factor is essentially a measure of confidence. The Agency almost always acts under conditions of uncertainty, but that uncertainty has an enormous range. Similar cost-effect relationships may look very different to the risk manager if they differ substantially in the weight of evidence tying pollutant to effect, or control strategy to reduction in risk.

Cost and effect as we have defined them are, of course, related; examination of that relationship is at the heart of risk management. Greater reductions in the harmful effect are usually associated with higher control costs, typically along a curve of declining efficiency. That is, the last increments of pollution control are far more expensive than the first. We may find, for example, that it costs as much to get from 95 to 99 per cent removal of some toxicant as it did to get from zero to 95 per cent.

There are a number of analytic tools that are aimed at exploring this relationship, which may be briefly distinguished:

■ Benefit/cost analysis

This approach weighs the costs of control, explicitly and directly, against the monetized benefits of control — the avoidance of disease and the attainment of other social goods (e.g., increased visibility, reduced soiling and materials damage, etc.). Optimal use of benefit/cost analysis occurs when all factors affected by a decision can be accurately represented in dollars. This is often difficult to do, since the Agency is frequently concerned with protecting such things as human life and the stability of ecosystems, social values for which there is no market price, or for which current procedures for finding "shadow prices" are bitterly controversial. In areas where this is not a constraint (cost of control vs. avoided crop or materials damage, for example) benefit/cost analysis provides a structured way to balance effects and costs directly.

■ Risk-benefit analysis

Risk-benefit analysis balances the economic benefits of a polluting activity against the associated risks to health and the environment. For example, the benefits of *using* a pesticide (e.g., the value of the increased crop yield minus the application cost) are explicitly weighed against the risks generated by the pesticide's use. Note that benefits do not refer to the benefits from regulation, but rather to the benefits from the use of the chemical. Because risks are not reduced to commensurate units (dollars), risk-benefit analysis is most appropriate when the Agency must balance one or two types of risk against the economic benefits of an economic activity.

■ Cost-effectiveness analysis

Unlike the other two approaches, cost-effectiveness analysis begins by accepting the desirability of a particular control action. It does not weigh risks against benefits, or monetize benefits; it only looks for the least-cost path to achieve a given goal, such as the achievement of a protective standard. For example, if a number of controls are available to remove some pollutant from the atmosphere down to a certain pre-determined level, the cost-effective solution is the one that does this most cheaply.

Cost-effectiveness analysis is at present the most frequently used risk management tool at EPA, since so much of the Agency's work is involved with implementing pollution standards. It is straightforward in application: in a simplified version, for example, one calculates the cost-per-ton removed associated with the available

options and, all other things being equal, picks the lowest. But cost-effectiveness analysis can also be used to compare different ways of obtaining some specified degree of risk reduction. An integrated method for doing this is summarized later in this chapter.

While these types of analysis could be part of any particular risk management exercise, it is important to note that risk management does not, as some critics have implied, demand the inappropriate monetization of the social values the Agency is charged with protecting. Risk management in the EPA sense is the expression of the value of the societal and governmental expenditure represented by an environmental control action. The value expressed could be relatively easy to quantify (e.g., reduction in materials damage or cases of particular diseases) or difficult — protection of sensitive ecosystems or future groundwater use. Risk management is a way of explaining the logical connections between a body of research, the application of certain economic, political and social values, and the achievement of some environmental result.

Inherent in risk management is the idea of comparability. The Agency has a number of goals, some of which may conflict. For example, deep ocean dumping of sewage sludge may reduce human health risk in comparison with incineration or land spreading, but may have adverse effects on marine ecosystems, which are valued in their own right, and on the human food chain. Assigning resources on the basis of the varying importance attached to the attainment of different goals, and coordinating efforts that are driven by apparently conflicting goals, are both susceptible to a risk management approach. Indeed, it is hard to see how they could effectively be done otherwise.

Also inherent in risk management is the principle of consistency. Since pollution control (and hence risk reduction) is an incremental process, with the later increments typically costing more to achieve than the earlier ones, the Agency may be faced with a number of potential actions with widely differing marginal costs for the same or similar risk reduction. It does not make sense to buy dear what you can get cheap.

Marginal cost consistency, however, may conflict with another sort of consistency of result. We may want to please an absolute limit on the risk experienced by any particular individual from environmental contaminants, or, in cases where residual risks are unavoidable, we may want to achieve a consistent level of post-regulatory risk in all control actions.

But proposals to establish absolute regulatory levels, however attractive they may be in terms of rational management, are constrained by a sense of the limits of quantification methods. Some important things cannot be quantified, but are nonetheless real. The Agency will not be allowed to undertake risk management if the public does not trust our response to their perceived concerns. Strictly quantitative models usually do not make allowances for such imponderables as public confidence; this is why risk management at EPA is not just numbers. And, of course, we will always be limited by the uncertain nature of environmental research and economic data, and we wish to take care not to read into such numbers more precision than their origins warrant.

Although we feel that the movement toward greater quantification of environmental decision variables is a good trend, the limitations noted above make it unwise to establish formal trigger points for Agency actions. It is not appropriate, for example, to settle on a single level of risk that would be required before we would consider regulatory action. Measures of consistency of result, such as marginal cost per case avoided, are useful guides; they should not be made into rigid grooves that might deprive the Agency of the flexibility it needs to carry out its complex missions.

On the other hand, consistency of *approach* in making decisions based on risk, cost, and uncertainty is essential. The management of EPA needs to know how the actions of the various programs actually work *all together* to reduce the harm done by pollutants. Management should also have the opportunity to compare the relative impact of the programs.

In order to determine current risk management approaches the Toxics Integration Task Force carried out a study of how the various considerations that make up risk management were used in 27 recent Agency regulatory actions. The study showed significant variations across programs in the way risk management was actually carried out. As mentioned earlier, risk management implies some balancing of values; the statutes differ in the way they direct us to balance values, particularly in the extent to which control costs may be considered in establishing allowable or "safe" levels of a pollutant.

Part of the difficulty in comparing risk management across programs arises because risk reduction does not even appear as an explicit concept in several of the Agency's statutes. Thus, when applied to a program that protects mainly environmental values via technology-based standards, such as the Effluent Guidelines Pro-

gram, risk management means something different from what it means in connection with a program (like the Hazardous Air Pollutants Program) focused on human health protection. Similarly, it is easier to present risk management decisions in the case of a national program to control a single substance than when, as in the Solid Waste Program and Superfund, we control complex waste streams. Further, programs responsible for cleaning up wastes (e.g., Superfund) or for controlling useful substances that are poisonous (pesticides and toxic industrial chemicals) have ways of expressing risk management information that are different from those used by programs that impose pollution controls in the usual sense.

Differences in mandate and program structure, however, do not excuse the Agency from developing consistent approaches in the areas of risk management to which the statutes are silent. The retrospective study found that the Agency as a whole had no generally accepted way of expressing the degree of confidence in the pollutant-effect connection or of dealing with intermedia transfer of risk. Moreover, despite their historic differences in approach, EPA programs are part of a single national effort embodied in a single Agency. The Agency in turn must respond to a basic requirement of good public policy: *to establish the connection between some expenditure and some recognized public good.* Most regulations cost something, whether expressed in dollars spent by industry or in terms of the consequences of doing without a useful product. All regulations use up Agency resources. Agency management needs to assure that the total of Agency and societal resources devoted to the prevention of harm to human health and the environment is being applied efficiently.

C. CURRENT RISK MANAGEMENT INITIATIVES

We understand the difficulties of applying risk management principles in an Agency as complex and as variously mandated as EPA. The risk management effort at the Agency therefore consists of a wide range of activities affecting nearly every aspect of the Agency's work. These activities fall into three broad classes. First, we want to obtain a better and more consistent information base for making decisions about the control of risk. Second, we want to use the various analytic methods associated with risk management whenever appropriate in developing environmental policy; we also want to place more emphasis on figuring out what we have achieved in terms of risk reduction through past efforts and on locating and efficiently managing the serious risks remaining. Third, we must communicate to the public what we are doing, why we are doing it in risk management terms, and how the risk management approach will improve the way that EPA carries out its mission.

1. Building the Information Base

No matter what risk management techniques are appropriate to a particular program (and these may legitimately vary), there should be a uniform way of reporting and recording these decisions. We have therefore developed a uniform format for presenting a summary of risk management information to EPA management, including the Steering Committee (which oversees the development of major rules), staff and program Assistant Administrators, the Deputy Administrator, and the Administrator. The risk management format solicits information regarding exposure, intermedia transfer, and the benefits and costs of regulation. Space is provided in the form to record both health risk reduction and "benefits other than risk reduction," such as prevention of damage to ecological systems, preservation of endangered species, or other factors.

We believe that using the form within the regulatory development process offers the following advantages:

— It will provide data for analyses of the variations in risk management practices across programs much more clearly; it will also note where these variations are necessary and appropriate.

— Using the form may help sharpen our perception of what the underlying technical problems are in evaluating complex risks, and how they ought to be presented for decisions.

— By documenting the expected nature and extent of pre- and post-regulatory risks, it should be possible to increase consistency here. Uniformity, however, is not the goal. Variations among statutes and individual circumstances require that this area be kept flexible.

— By documenting intermedia transfer, the format should improve our ability to track risk in the environment as a whole.

We have also instituted an Options Selection Process as a way of providing consistent policy guidance from senior Agency management throughout the entire course of regulatory development. For this process, every important regulation or other policy-setting action the Agency takes is evaluated at an early stage of its development by the Deputy Administrator. Review criteria include level of environmental risk reduction, net benefit to society, flexibility, and propensity to encourage environmentally acceptable innovation. The Deputy Administrator and other senior EPA

managers can review not only the particular regulatory option that a program recommends, but also the other options considered, the applicable decision rules, the data on which the recommendation is based, and the rationale for selection. The Options Selection Process should ultimately increase the efficiency of EPA's operations by involving senior EPA management from the very beginning of regulatory development.

2. *Using Risk Management Tools*

The purpose of the analytic tools used in risk management is, naturally, to help determine the most efficient way to reduce risk, which implies the establishment of the risk (or effect) measure and analysis of the impact some risk-reducing action has on other social values. This often represents a departure from the past analytic practices.

■ Benefits Assessment

As the Agency turns its attention increasingly toward controlling toxic chemicals, it is important to do more than simply calculate the magnitude and distribution of costs for each alternative considered. We have to evaluate benefits as well as the costs, identifying what new controls are buying in the way of additional health or environmental improvements. Only by expressing all potential actions in terms of what will result from them —broadly speaking, their risk-reduction effect — can we select those actions that benefit the environment to the greatest degree. Choosing intelligently among risk targets in this way is not possible without some way of estimating benefits.

Estimating benefits is generally more difficult than estimating costs. It requires more extensive data and more sophisticated techniques. We have to rely on often sparse information from such areas as risk assessment, dispersion modeling, and other scientific fields, coupling this with imperfect information about how the public values the many factors that figure in environmental decisions. Despite the difficulties, however, EPA has made significant progress in this area over the last several years, and we believe that the effort pays off in more consistent and defensible decisions.

Some of the advantages of using benefits assessment are made clear by the recent example of work done on lead in gasoline. Our analysis included a comprehensive assessment of the benefits that further regulation would provide.

The cost/benefit analysis produced the following findings:

- Our analysis and other major studies both in the U.S. and abroad indicated that the amount of lead in blood is directly related to the amount of lead in gasoline. Children with elevated blood levels require medical monitoring and sometimes treatment. The costs of these, not to mention the pain and suffering incurred, are substantial.

- Recent EPA surveys indicate that over 12% of all cars equipped with catalytic converters to control auto emission are currently being "misfueled" with leaded gasoline to take advantage of cheaper leaded gas or to obtain higher octane. Misfueling poisons catalysts and substantially increases other auto pollutant emissions. Given current misfueling rates, misfueled vehicles will account for one-third of leaded gasoline demand in 1988, significantly increasing our estimates of future lead and other pollutant emissions. The impact of these unanticipated emissions on public health and welfare is substantial, and can be quantified.

- Lead forms corrosive compounds that increase automotive maintenance costs. Cars that use leaded gasoline need more frequent tune-ups, exhaust system replacements, and oil changes. These too involve costs that are measurable for the country as a whole.

The analysis showed that economic impacts described above are substantially larger than the increased costs of producing gasoline with reduced lead content, even though many of the projected health impairment effects were not monetized.

- Cost-effectiveness analysis

At a more general level, we have begun to develop an integrated methodology for applying *risk-based* cost-effectiveness analysis to regulatory decisions. This Integrated Environmental Management approach is the first attempt to analyze, in quantitative terms, the regulatory inefficiencies created by the Agency's decentralized structure, and to propose specific remedies. To do this it estimates the amount of health and environmental risk reduction that has been bought for each regulatory dollar that an industry has spent. It keeps track of the cumulative costs of regulations of specific industries, the relative importance of different regulations in reducing risks, and shifts of pollutants among environmental media. The ultimate goal of these integration studies is to find the combination of controls that achieves the most risk reduction for any specified cost or the leastcost way of arriving at any specified level of risk reduction.

Integration studies attempt to bring together all the useful information (e.g., data on production and processes, emissions and effluent levels, and costs of controls) that EPA possesses on a particular pollution source or set of sources. These could be industrial sectors, publicly-owned sewage plants, or combinations of sources in particular geographic areas. The methodology then uses exposure models to trace pollutants through air, water, ground water, and land, so as to estimate human and environmental exposures in particular places or in modelled environments representative of where plants in particular industries are located.

Using research on health and environmental effects associated with these pollutants, it then estimates the effects that may be generated as a result of such epxosures, and combines these data in a decision model similar to those used elsewhere in industry and government to solve complex strategic problems. The transfer of pollutants among media is tracked and calculated throughout the analysis. The result is a set of specific cost-effective control strategies for a geographic area or for some characterizable source such as an industry, based on particular environmental conditions.

One of the major findings of this work is how radically the relative cost-effectiveness of many controls changes when one modifies important environmental variables, such as population distribution and density, topography/meteorology, the volume of receiving waters and so forth. The lesson here is that risk management is eventually going to require looking more closely at the projected effects of pollutants *where the pollutants are actually found.*

■ Managing for environmental results

EPA has always experienced some difficulty in relating its actions to the actual reduction of risk. Given the language of the statutory mandates, programs have typically placed more emphasis on mandating emission or effluent controls than on determining what effect such controls had on the actual environment. This approach was, of course, indispensible in the early days of environmental protection. The need for controlling gross pollution was so pressing that the Congress opted for an easily administered and implementable set of regulatory tools.

At present, however, with ten or so years of pollution control behind us, fixing the precise nature of the remaining problems is much more difficult. Also, we have created an enormous apparatus for controlling pollution; as we add more increments to it, it would be well to determine its impact on the values the Agency is mandated to protect. These realizations have led to a general policy

we call managing for environmental results, which may be considered the business end of the risk management approach.

An immediate outcome of this policy is the requirement that programs include in their budget submissions statements about what environmental results requests for funding are designed to achieve. In addition, the Agency is implementing a national monitoring strategy designed to meet the full range of current and future needs for environmental data, so that we can effectively tie our policies to actualimprovements in environmental quality. We are also beginning to shift our enforcement priorities toward compliance measures based on actual risk reduction, rather than simply examining the numbers of court referrals or administrative orders.

3. Strengthening the Role of Communication in Risk Management

This document has touched in a number of places on the importance of communication in risk management. The point cannot be made too often. In one sense, risk management *is* a form of communication. Technical analysis of the costs and benefits of a proposed action is not a device for coming up with the "right" or "rational" answer; all such analyses are far too sensitive to subjective values and far too dependent on uncertain data for us to pretend that they are. Risk management, and the technical analysis that contributes to it, is largely the *exposition* of the information we believe is reliable, the values we wish to apply and the way that these two are linked to produce a set of policies. The information is derived from the best science we can find or commission although it is important to note that even the scientific parts of a risk management decision are touched with value considerations and are generally not testable under ordinary scientific canons. The values are derived first of all from our statutory charters and the judicial interpretations that have grown up around them and from the legitimate exercise of judgment and choice by politically appointed Agency managers.

Obviously, not everybody will agree with the values so expressed, but in order for the debate about values to begin and for the democratic processes that ultimately establish values to take place, everyone has to know what the values underlying our decisions really are. If they are hidden behind a facade of "rationality" the debate is never joined. The frank expression of our values, of our uncertainties, and of the trade-offs involved in every important decision about environmental protection is itself a central value of EPA. It is this value that drives the set of current practices and policy initiatives we are calling risk management.